

Attorney Docket No.: DRE-0055
Inventors: Laurencin et al.
Serial No.: 09/878,641
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REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. New claim 12 has been added. Support for this amendment is provided in the specification at page 8, line 22, page 9, lines 22 through 31, and page 12, lines 5 through 12. Thus, no new matter is added by this amendment and entry is respectfully requested. Reconsideration is respectfully requested in light of this amendment and the following remarks.

Rejection of Claims 1-11 under 35 U.S.C. § 103(a)

The rejection of claims 1-3 and 6-9 under 35 U.S.C. § 103(a) as being unpatentable over Wolowacz et al. (WO 95/01810 A1) in view of Chervitz (U.S. Patent 4,917,699) has been maintained.

The rejection of claims 4, 5, 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Wolowacz et al. in view of Chervitz as applied to claims 2 and 8, and further in view of Vacanti (U.S. Patent 5,855,610) has also been maintained.

Arguments and the Declaration by Dr. Frank Ko presented by Applicants in the response filed June 7, 2005 were deemed unpersuasive by the Examiner. In particular, the Examiner suggests that the Declaration compares the claimed subject matter to the Chervitz reference, which is not the closest

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prior art. Instead, the Examiner suggests that Wolowacz et al. is the closest prior art. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to look to the teachings of Chervitz to modify the standard braided scaffold of Wolowacz et al. to a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments.

Applicants respectfully traverse this rejection.

It is respectfully pointed out that the Examiner has failed to address arguments and evidence set forth by Applicants in the last response which rebut any prima facie case of obviousness over the cited combination of prior art references.

MPEP 2144.09 is clear; a prima facie case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. In the last response, beginning at page 5, as well as in Dr. Ko's Declaration at paragraph 5, evidence was pointed to in the specification demonstrating that the fiber architecture of the three-dimensional braid of the present invention provides for a variable microstructure for unexpectedly enhanced cell in-growth. In particular, experiments are outlined in the

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specification at page 7, lines 9 through page 8, line 24, demonstrating that the fiber structure of the 3-dimensional braided scaffold of the present invention provides the scaffold with unexpectedly advantageous and superior properties with respect to cell in-growth as compared to other scaffolds prepared from the same polymeric fibers. Specifically, fibroblasts organized along the length of the fibers and osteoblasts showed a distinctly different morphology as compared to fibroblasts with the 3-dimensional braided scaffolds of the present invention. In contrast, cells did not organize and morphology of cell types was not distinct in a microfiber, non-woven mesh scaffold prepared from the same biodegradable polymeric fibers. Also see paragraph 5 of Dr. Ko's Declaration.

The cited prior art references are silent with respect to cell in-growth varying depending upon the geometry of the scaffold. Thus, the enhanced cell in-growth observed using 3-dimensional braided scaffolds of the present invention as compared to other scaffolds of the same material is clearly an enhanced property not predicted or expected from the cited combination of prior art references. Further, the importance of cell in-growth and promoting formation of ligament or tendon tissue to the scaffold is discussed in detail in the Background Section of the patent application (see e.g. page 3, line 13 through page 4, line 5), thus

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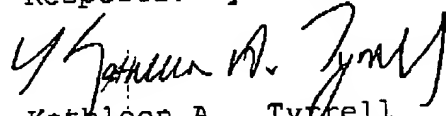
demonstrating that the results at page 7, lines 9 through page 8, line 24 of the instant specification are of a significant, practical advantage, as required by MPEP 716.02(a). Accordingly, evidence of the unexpected superior cell in-growth in the three-dimensional braided scaffolds of the present invention set forth in the instant specification overcomes any prima facie case of obviousness from the combined teachings of Wolowacz and Chervitz and Wolowacz, Chervitz and Vacanti.

Withdrawal of these rejections under 35 U.S.C. § 103(a) is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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